October 29, 2004

TO: The Secretary
Through: DS _____
COS _____
ES _____

FROM: Director, NIH

SUBJECT: Federal Managers' Financial Integrity Act (FMFIA) of 1982 – *Annual Assurances of Compliance* – INFORMATION

PURPOSE

The purpose of this memorandum is to provide the necessary assurances of and information on National Institutes of Health (NIH) compliance with the FMFIA (31 U.S.C. 3512). It is prepared in accordance with Office of Management and Budget (OMB) Fiscal Year (FY) 2004 reporting requirements and covers Section 2, *Internal Controls,* and Section 4, *Financial Systems.*

I, Elias A. Zerhouni, NIH Director, state and assure that to the best of my knowledge:

(1) The system of internal controls of this agency, except as indicated under (5), is functioning and provides reasonable assurance as to the efficiency and effectiveness of programs and operations; the reliability of financial and performance information; and compliance with laws and regulations. These controls satisfy the requirements of the Federal Managers' Financial Integrity Act § 2.

(2) The financial management systems of this agency, except as indicated under (5), provide reasonable assurances that obligations and costs are in compliance with applicable law and performance data and proprietary and budgetary accounting transactions applicable to the agency are properly recorded and accounted for to permit the timely preparation of accounts and reliable performance information. The financial control at this agency satisfies the requirements of the Federal Managers' Financial Integrity Act § 4.

(3) The system of internal controls of this agency that relates to the security of financial management systems and performance and other financial data, except as indicated under (5), provides protections commensurate with the risk and magnitude of harm resulting from loss, misuse, or unauthorized access and satisfies the requirements of § 5131 of the Clinger-Cohen Act of 1996, § 5 and 6 of the Computer Security Act, and § 3533(D) (2) of the Government Information Security Reform Act.

(4) The financial management systems of this agency, except as indicated under (5), provide this agency with reliable, timely, complete, and consistent performance and other financial information to make decisions and efficiently operate and evaluate programs and satisfy the requirements of the Federal Financial Management Improvement Act § 803(a), the Government Performance and Results Act, and *OMB Circular No. A-11 Preparation and Submission of Budget Estimates*. A remediation plan under FMFIA ( ) is (X) is not required.

(5) I am monitoring and employing techniques that mitigate the material weaknesses, as follows:

Description of material weakness	Current status	Resolution target date
Financial Reporting Systems	Corrections in process	2007 or completion of the NBRSS

ASSURANCE STATEMENT, SECTION 2

NIH is committed to ensuring effective management controls and clearly demonstrating and documenting them in its extramural, intramural, and administrative program areas. During FY 2004, we continued to successfully integrate management controls into program and administrative areas in support of our biomedical and behavioral research mission. We use a multifaceted approach to evaluate the efficacy of our management controls, which includes Management Control Reviews, Alternative Management Control Reviews, General Accounting Office (GAO) Reviews, Office of Inspector General Audits, Corrective Action Reviews, Corrective Action Plans, Program Evaluations, and Management Reviews conducted by both internal and external groups.

A total of 160 program reviews—26 intramural, 62 extramural, and 72 administrative—were ongoing or completed at NIH in FY 2004 (see enclosure E for an inventory of the reviews). In addition, we anticipate that the NIH Division of Program Integrity will open 87 new cases, review 37 cases that were opened in prior fiscal years, and close 57 cases. These reviews include an evaluation of systemic controls when related management

controls are found to be lacking or ineffective. Below are examples of proactive reviews that have improved or will enhance management controls for NIH's intramural, extramural, and administrative activities.

INTRAMURAL ACTIVITIES

Program Reviews

In FY 2004, both the National Institute of Child Health and Human Development (NICHD) and the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) moved forward with their Blue Ribbon Panel Reviews, conducting the initial meetings April 27 and June 2, respectively. The purpose of these reviews is to improve the intramural programs in the respective Institutes. Final reports will be reviewed by the Deputy Director for Intramural Research (DDIR) and the Director, NIH.

The NIH Director's Blue Ribbon Panel on the Future of Intramural Clinical Research reported to the Advisory Committee to the Director in 2004. This Panel, chaired by Dr. Edward Benz, Director, Dana Farber Cancer Institute, and Dr. Joseph Goldstein, Professor of Medicine, University of Texas Southwestern Medical Center at Dallas, recommended revision in the oversight structure of NIH intramural clinical research. As a result, the Advisory Board for Clinical Research was created and began its work in September 2004. Other recommendations concerned improved training and career pathways in patient-oriented research; the role of the NIH in conducting distinctive, high-risk, clinical research; and the need to reduce administrative burdens in the conduct of clinical research.

The DDIR chaired the annual public meeting of the Chairs of the NIH Boards of Scientific Counselors (BSC) on February 6, 2004. BSCs are duly constituted Federal advisory committees established to advise the Institutes and Centers (ICs) on the quality of the intramural research being conducted. Recommendations made by the BSC Chairs were transmitted to the Scientific Directors for consideration. This group will conduct its next meeting in the spring of 2005.

Intramural Safety Activities

The Division of Occupational Health and Safety (DOHS), Office of Research Services (ORS), completed a review of the safety surveillance programs provided at the NIH Clinical Center. A description of these surveillance programs was submitted to the site-survey team in support of the Joint Commission for the Accreditation of Healthcare Organizations (JCAHO) and the College of American Pathologists (CAP) review of the Clinical Center. The programs were determined to be fully acceptable and met the accrediting criteria of those organizations.

The DOHS is currently engaged in a comprehensive evaluation of the services it provides to the intramural research community. This review, as part of the Performance Management Plan process, is centered on three major program areas: occupational safety and health services; occupational medical services; and integrated pest management services. Services are evaluated through customer surveys of the NIH research community and other quantitative measures (e.g., benchmarking) to determine the level of effectiveness and customer satisfaction.

The NIH safety program has been participating in the establishment of the HHS Departmental Occupational Safety and Health Council. This interagency workgroup is currently reviewing the HHS Safety Manual, which will be used to provide guidance and procedural recommendations on occupational safety and health issues. Also under consideration by the Council is the institution of a Department-wide site review of the safety programs within each OPDIV.

NIH participation in revision of the Centers for Disease Control and Prevention publication, *Biosafety in Microbiological and Biomedical Laboratories* (HHS 93-8395), has resulted in broad collaboration between the NIH safety program and biosafety experts in both the public and private sectors. This publication is the standard biosafety reference, and revision of it will result in the implementation of updated guidelines and recommendations that will be used nationally and internationally.

Animal Care and Use

The NIH has three standing oversight subcommittees of the Animal Research Advisory Committee that are charged with reviewing the scope and implementation of three trans-NIH programs: occupational safety and health, centralized training, and security and disaster preparedness. Following the last Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC) peer review site visit in 2002, the newly formed subcommittees issued the second annual series of recommendations to further improve practices involving the delivery of the three trans-NIH services. Upon receipt of those subsequent subcommittee recommendations, the AAALAC awarded Full Accreditation to the NIH Intramural Research Program in January 2003.

The IC Animal Care and Use Committees oversee all intramural research involving animals and conduct semiannual in-depth reviews of all aspects of NIH animal care and use programs. These reviews include not only the examination of facilities and animal procedures managed by the ICs, but also the adequacy and interrelationship of support services, which include occupational safety and health and engineering services critical to the safe and efficient operation and maintenance of animal research facilities.

The next triennial AAALAC peer review site visit will occur in the summer of 2005.

Intramural Assessment of Management Controls

The Intramural Assessment of Management Controls is an annual process that requires the Scientific Director of each IC to carry out a self-assessment of management controls. The Office of Intramural Research (OIR) is reviewing and analyzing IC submissions to ensure that effective management controls are fully integrated into intramural and administrative program areas.

Graduate Medical Education

The Accreditation Council for Graduate Medical Education (ACGME) reaccredited the program for Infectious Diseases and Rheumatology and accredited Hematopathology for the first time. Mandated internal reviews were conducted for Endocrinology and Metabolism, Hematology, and Medical Oncology. The American Board of Hospice and Palliative Medicine granted the Pain and Palliative Care Program accreditation; it is one of nine programs nationally to achieve this recognition.

Continuing Medical Education

In April 2004, the NIH submitted its annual report to the Accreditation Council for Continuing Medical Education (ACCME). Our continuing medical education program accredited 258 activities, representing 2,295 hours of instruction and serving 35,751 physicians and 40,264 nonphysicians locally, nationally, and internationally.

Continuing Education

In June 2004, the Continuing Professional Education Committee of the American Psychological Association granted the NIH Continuing Education Program for psychologists continued approval. A total of 13 activities provided 253 credits to 672 psychologists.

Review of Human Subjects Research

From January 2004 to March 2004, the Office of Human Subjects Research (OHSR) conducted an assessment of liability issues relevant to the 200 members of the NIH's 14 Institutional Review Boards (IRBs). OHSR operates within the Office of the Deputy Director for Intramural Research. In May and June 2004, OHSR met with each of the IRBs and provided them with information regarding member liability.

In October 2003, OHSR initiated an assessment of the NIH Intramural Research Program clinical research protocol approval process in an effort to identify ways to manage the process more efficiently. The assessment remains in progress.

Technology Transfer Activities

In 1993, the Division of Management Policy (predecessor of the Office of Management Assessment) found a material management control weakness in the Office of Technology Transfer (OTT). In January 2004, OTT submitted its final Report of Technology Transfer Corrective Action Items documenting completion of the remaining corrective actions. The Technology Transfer Corrective Action Review is now closed, with the finding that all remaining corrective actions have been satisfactorily completed.

As part of its Work Plan for Fiscal Year 2004, the HHS Office of Inspector General, Office of Audit Services, is conducting an audit of NIH royalty income from intramural inventions. The review will determine whether NIH receives the royalty income to which it is entitled, royalties are calculated correctly, and payments are received in a timely manner. The audit began in June 2004 and is expected to take one year to complete.

EXTRAMURAL ACTIVITIES

Proactive Compliance Site Visits

In FY 2004, the NIH Office of Extramural Research (OER) conducted six proactive compliance site visits to Georgia State University (5/11/2004), Emory University (5/12/2004), Carnegie Mellon University (7/13/2004), University of Pittsburgh (7/14/2004), Roswell Park Cancer Center (8/24/2004), and State University of New York at Buffalo (8/25/2004). The site visits minimize or eliminate incidences of noncompliance before problems arise by assessing the level of understanding that university staff have of Federal and NIH requirements through discussions of policies, procedures, and practices at recipient institutions.

Improvements resulting from the site visits are consequently made at the institutions. NIH then analyzes and disseminates information on successful strategies to deal with compliance challenges. This compendium of findings and observations is updated every two years and serves as an on-line resource for NIH's extramural grant recipients.

Reduction of Administrative Burden on the Grantee Community

Beginning in FY 2000, the NIH instituted a modular grant application process for certain grant applications requesting $250,000 or less in total direct costs in any year. The intent was to focus the efforts of the investigators, institutional officials, and NIH staff on the science of the applications, reduce the administrative burden, accommodate investigators' need for flexibility, and, in general, facilitate science while simplifying administration.

In FY 2003, the NIH initiated a contract with Westat to evaluate the modular process to determine whether the process is in fact meeting its stated aims and reducing the administrative burden on the applicant community. Phase I of the evaluation has been completed and consisted of establishing and testing survey instruments for various stakeholder groups. Phase II, the administration of the survey instruments and subsequent analysis of results, began in FY 2004.

Grant Oversight Processes

In FY 2004, OER completed the development and initial administration of a Management Controls Assessment Questionnaire for Extramural Research to help NIH ICs identify potential areas for improved compliance with both NIH and their own established policies and procedures. The results are being analyzed to identify management areas across the NIH extramural program that need strengthening to provide continued assurance that the NIH provides effective stewardship of federal funds. Following review and analysis, the NIH will consider implementing recommendations for improvements. The instrument will be administered biennially to allow ICs to track progress.

National Research Service Awards Payback Center Outcomes

A 1999 Office of Inspector General audit of the NIH Ruth L. Kirschstein National Research Service Award (NRSA) program identified problems with the program's database. In response, Payback Service Center functions and responsibilities were transferred from the National Institute of General Medical Sciences to the Office of Extramural Research within the Office of the Director, NIH.

Since the transfer, the NRSA Payback Service Center has processed and closed 1,194 trainee and fellowship obligation files in 2001, 2,150 files in 2002, and 3,340 files in 2003. A total of 1,307 delinquent trainee and fellowship files for these same years were forwarded to the Office of Financial Management for further processing, after the NRSA Payback Office made multiple attempts to obtain required follow-up information from the trainees and fellows involved. Total amounts collected from NRSA recipient payback reimbursments were $401,065 in FY 2001, $474,499 in FY 2002, and $566,833 in FY 2003.

Biomedical and Behavioral Scientists

The NIH independently, and in conjunction with the National Academy of Sciences (NAS), monitors and assesses the national need for research personnel and develops and implements strategies for improving the NRSA program.

The NAS is currently conducting such an assessment, with results anticipated to be released in the fall of 2004. The NIH continues to work with other federal agencies, research training and funding organizations, and national scientific societies to assess and address current and future challenges facing postdoctoral research trainees. These issues include the role and importance of Postdoctoral Offices at research institutions and opportunities that will help foster the transition of promising postdoctoral fellows and trainees to independent research positions.

On June 17-18, 2004, the NIH co-sponsored a workshop entitled "Support of Graduate Students and Postdoctoral Researchers in the Sciences and Engineering: Impact of Related Policies & Practices" with the National Science Foundation and the Council of Graduate Schools. The workshop evaluated the role and impact that student financial support plays in encouraging U.S. citizens to pursue and complete doctoral and postdoctoral studies in science, technology engineering, and mathematics. The workshop identified critical variables that will need to be considered by funding agencies when setting future predoctoral and postdoctoral stipend levels.

Reporting of Patents and Inventions

In FY 2004, the NIH continued to increase efforts to improve grantee and contractor patent and invention reporting compliance by hiring additional data entry contractors and expanding Web page information and assistance, and through outreach efforts. The NIH is holding a minimum of six seminars on invention reporting and the Bayh-Dole Act and seven Interagency Edison (iEdison) training workshops and participated in six Proactive Compliance Site Visits between March and September 2004.

The newly enhanced, Internet-based iEdison system continues to ease the reporting and compliance burdens of our grantees, contractors, and internal agency management. The iEdison system currently receives over 4,100 invention disclosures annually and automatically sends e-mail notifications to grantees or agency officials of 15 different time-critical decisions on intellectual property reporting. The June 2004 deployment now enables users to input Data Universal Numbering System (DUNS) numbers. Further, as of June 2004, 21 federal agencies (two more than the previous year) had elected to use the iEdison system for their invention reporting.

Electronic Research Administration

The Electronic Research Administration (eRA) project continues to implement new electronic tools to facilitate and improve the management of extramural research grant activities. In August 2003, the Assistant Secretary for Administration and Management determined that eRA had the capability to become the DHHS enterprise system for research grant management. Consequently, eRA recently began serving as the single HHS research grant system for all of its operating divisions. The CDC began using eRA

in 2004, and other OPDIVs will start in 2005.

The eRA system implemented the Internet Assisted Review module in the spring of 2003, which has decreased the amount of time it takes to complete the peer review of applications and has increased the efficiency of review staff. Furthermore, the system began digital data streaming of selected grant applications in the fall of 2003. This new program module enables program officials to administer their portfolios using the paperless business processes mandated by Congress.

eRA is currently piloting electronic progress report submission through the Commons; more than 550 progress reports have been submitted electronically. In November 2003, the Commons gave organizations the capability to submit just-in-time grant application material and execute no-cost extensions electronically. The Web-based grant closeout application, introduced in spring of 2002 for NIH staff, will be extended to external users such as principal investigators and offices of sponsored research in 2004.

Finally, the NIH now regards electronic documents and data stored in the eRA and IC databases as legitimate components of the official grant file. This new policy was established in August 2003. The NIH's official acknowledgment of electronic files is in accordance with HHS Grant Policy Directive, Part 3.06: *Post-Award Reports and Records*. Certifying electronic documents and data is a necessary step toward realizing the eRA's goal of developing a state-of-the-art, electronic grant-processing system that will substantially reduce the need for paper during every phase of the grant cycle. The new policy is also consistent with the President's Management Agenda and Public Laws 105-277 and 106-107.

ASSURANCE STATEMENT - SECTION 4

NIH financial systems, as a whole, satisfy most policies and standards prescribed for executive agencies in developing, operating, evaluating, and reporting on financial management systems as defined in OMB Circular A-127, *Financial Management Systems*, and OMB's *Implementation Guidance for the Federal Financial Management Improvement Act (FFMIA) of 1996*.

There are instances, however, in which our financial systems, including the financial portion of mixed systems, do not fully conform to all Government-wide standards. These standards require that agency financial management systems comply with the following requirements:

- Systems must use an agency-wide financial information classification structure.
- All financial and the financial portion of mixed systems must be integrated.

- Systems must use the U.S. Government Standard General Ledger at the transaction level.
- Systems must comply with applicable Federal accounting standards.
- Systems must meet all financial reporting requirements.
- Systems must capture and produce financial data to measure program performance.
- Systems must comply with the functional requirements of the Joint Financial Management Improvement Program.
- Systems must ensure that internal controls exist for all inputs, processing, and output functions.

Ernst & Young reported in its FY 2003 *Report of Independent Auditors on Compliance with Laws and Regulations* that it performed tests to determine whether NIH financial management systems substantially comply with Federal financial management system requirements, applicable accounting standards, and the U.S. Standard General Ledger at the transaction level. The results of its tests disclosed instances in which NIH's financial management systems did not substantially comply with certain requirements.

As part of the FY 2004 Chief Financial Officer/Government Management Reform Act audit, we assessed our compliance with financial system requirements and with the Federal Financial Management Improvement Act, and we concluded that our financial systems, including mixed systems, do not fully conform to all government-wide standards required by OMB Circular A-127. To address these issues, we have strengthened compensating controls and revised the accounting system closing process.

Some mixed systems do not provide financial transactions to the central system using consistent processing rules. In addition, some systems are not fully and seamlessly integrated but are otherwise linked with the system. For example, the property management information system does not comply with financial systems requirements. The NIH Chief Financial Officer five-year plan indicated that NIH did not fully comply with all financial systems requirements.

REMEDIATION PLAN

To address these issues, we—

- launched a review and assessment of how NIH transacts business among all internal activities and customers to identify system integration and accounting requirements and
- awarded a contract for an NIH-wide business system, to include a Joint Financial Management Improvement Program-approved accounting system.

MAJOR REVIEWS

We initiated a review to address and resolve the material weaknesses cited in the audit of DHHS' FY 2003 financial statements. The review included NIH and contract audit staff and focused on the methodology and discipline applied to our fiscal year closing process. As a result of these efforts, we have implemented numerous additional analyses and reconciliations; we have implemented a new, more disciplined and controlled process to prepare the trial balances from which our financial statements are prepared; and we have identified additional areas of potential improvement on which we have already begun work. Also, we plan to validate or change certain internal processes and provide significant training to staff. This effort will result in benefits to accounting operations and to the administrative operations of ICs.

The Office of Financial Management, working with the NIH Center for Information Technology, has implemented a new Web-based tool that allows staff to analyze on-line all general ledger accounts individually and by transaction codes. This has allowed us to correct and compensate for some of the deficiencies noted by auditors. The information is more reliable and available in a timely manner for review and reporting.

FMFIA REPORT

The FMFIA report also includes the following documents and is available from Mr. Paul Coppola, Division of Quality Management, Office of Management Assessment, Office of the Director. He can be reached at (301) 496-2464.

Enclosure *A - Statistical Summary of Performance*

Enclosure *B - Progress Report of High Risk Areas* (none)

Enclosure *C - Schedule of Corrective Actions for Pending Material Weaknesses* (none)

Enclosure *D - Schedule of Pending Material Non-Conformances (Section 4)* (none)

Enclosure *E - Inventory of FY 2004 Reviews*

/s/

Elias A. Zerhouni, M.D.